IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Ajay Hasmukhlal UPADHYAY

Serial No.: 09/879,320

Filed: June 12, 2001

For: **COMPRESSION GUAIFENESIN COMPOSITIONS, METHOD FOR MAKING THE SAME AND METHOD FOR MAKING COMPRESSED GUAIFENESIN DOSAGE FORMS THEREFROM**

APPEAL BRIEF

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Date: August 24, 2010

(i) REAL PARTY IN INTEREST

The real party in interest is the assignee of the inventor's interest, Rhodia Inc., a corporation formed under the laws of United States of America having a principal address in Cranbury, New Jersey.

(ii) RELATED APPEALS AND INTERFERENCES

There is no known prior or pending appeals, judicial proceedings or interferences, known to Appellant, his assignee, or undersigned counsel which may be related to, directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

(iii) STATUS OF CLAIMS

Claims 2-4, 8, 33-34 and 37 stand finally rejected and are the subject matter of this appeal.

Claims 1, 5-7, 9-32, 35-36 and 38-42 all the remaining claims in the application, have been canceled.

(iv) STATUS OF AMENDMENTS

No amendment has been filed subsequent to the final rejection. However, a Request for Reconsideration was filed in response to the Final Rejcetion and was considered as noted in the Advisory Action dated June 8, 2010.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

The invention as defined in the sole independent claim, claim 37, is directed to a tablet formed by compressing in a tableting press, a free flowing granular composition comprising from about 85% by weight to about 97.5% by weight of the pharmaceutical guaifensesin; (Specification, page 5, lines 4 and 20-21).

Prior to the present invention, known guaifenesin compositions exhibited ingredients flow properties, that is, prior composites tended to flow relatively slowly or only with the aid of agitations (Specification, page 2, lines 10-14). In addition, the resultant tablets tended to exhibit

high friability, unacceptably low hardness, and tended to exhibit "capping", that is cracking and separation of part of the dosage form of the tablet (Specification page 2, lines 5-10).

Thus, the present appellants undertook the discovery of compositions of guaifenesin which would be suitable to form a tablet exhibiting less than 1% friability (specification, page 3, lines 9-12), a hardness in the range of 10.3 to 17.0 kp Specification, page 25 Table 2a) and resistant to capping (Specification, page 25, Table 2a (capping = 0)); formed by direct compression in a tableting press operating at no more than 2.5 tons (Specifieation, page 13, lines 11-12)

In order to achieve such a tablet, applicant provided a composition of about 85% to about 97.5% guaifenesin, about 1.0 to about 7% by weight of a polyvinylpyrrolidone binder (Specification, page 5, lines 7 and 28-31); about 0.2 to about 4% by weight of solubilizer, or disintegrant or solubilizer and disintegrant (page 5, lines 10-12) and from about 0.1 to about 2% of a lubricant (Specification, page 5, lines 16-18) in a certain particulate form such that a free flowing agglomerate of the guaifenesin and polyvinylpyrrolidone binder exhibts a flow rate greater than or equal to 6.5 gram/second as measured in VanKel flowmeter (Specification, page 11, lines 26-30).

The certain particulate form as defined in independent claim 1 is such that 0% of the particles exhibit a particle size greater than 425 micrometers and greater than about 85% by weight of the partieles exhibit a particle size greater than about 45 micrometers. See guaifenesin powder denoted as GP-A (made by the assignee Rhodia Inc) (Specification, page 13, lines 18-20 and tin the table at the top of page 14).

(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The rejection of claims 2-4, 8, 33, 34 and 37 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. Patent 6,372,252) in view of Dansereau et al. (U.S. Patent 5,032,406), Troy et al (U.S. Patent 3,627,583), and Wilbur et al. (U.S. Patent 6,623,756); or alternatively over Blume et al in view of Dansereau et al. and Wilbur et al.

(vii) ARGUMENT

Blume is alleged to teach immediate and sustained release compositions comprising guaifenesin. This composition is in the form of a tablet having two portions, a first portion beign an immediate release formulation of guaifenesin and the second portion being a sustained release formulation of guaifenesin (see abstract). Blume uses a hydrophilic polymer (a hydroxypropyl methylcellulose) (Specification, column 5, line 36 to column 6, line 23). The Examiner concedes (Final Rejection, page 3, line 8) that "Blume fails to teach granulation of guaifenesin with polyvinylpyrrolidone.

Apart from the Examiner's concession, applicant urges that Blume is not concerned with improving the properties of guaifenesin tablets to exhibit low friability, high hardness and resistance to capping of the presently claimed tablets. In fact, Blume's granulation is quite unlike that of the present invention (See column 8, lines 19-23). While Blume uses screen sizes rather than describing his particle size distribution, applicant had provided, with the RCE, filed October 26, 2007, an excerpt from Perry's Chemical Engineers Handbook, Sixth Edition, 1984 (page 21-15) Table 21-6 identifying sieve designation (screen size) and the resulting particle size. (A copy is attached in the Evidence Appendix from the Board's convenience).

There, it is shown that Blume's granulate, 10% of which is retained on a 10 mesh screen which has openings of 2.00mm (200 microns) is substantially larger than applicants largest particle size (0% greater than 425 micrometers). In fact, Blume's 100 mesh screen (150 microns) means that 60% of Blume's particle size lies within the range of 150-200 microns. This is in no way equivalent to the claimed range of independent claim 37.

What is important about these limitations on the nature of the agglomerate is that only these particular limitations can produce a tablet under relatively low pressure (not more than 2.5. tons) which exhibits less than 1% friability, a hardness in the range of 10.3 to 17.0 kp and is resistant to capping).

Having now compared the teachings of Blume with only independent claim 37, it can be seen that Blume clearly does not teach an agglomerate of guaifenesin and polyvinylpyrrolidone, Blume specifically teaches that his granulation far exceeds the maximum particle size permitted, i.e. Blume states his granulation has "not more than about 10% of the resulting granulation is retained on a 10 mesh screen" (about 2.0mm)-more than 400% larger than that permitted in the instant claim (see column 8, lines 22-23 of Blume et al.). While it is stated in Blume that the resulting formulation "may further be compressed on a tablet compressing machine using tooling to form tablets (Blume, column 8, lines 36-37) no disclosure of the pressure of the tabelting press, nor of the resulting tablet properties as far as hardness, capping and friability can be found within the four corners of the Blume et al. reference.

Faced with the serious deficiencies of the Blume et al. reference as a basic teaching reference for the claimed invention, the Examiner then attempts to cobble together the previously discussed Dansereau et al with the Troy et al. and Wilbur references. Even these references do not establish a prima facie case of obviousness.

Dansereau teaches a dual action tablet for immediate and sustained release, comprising an outer tablet and an inner tablet, respectively, where the inner tablet comprises guaifenesin and polyvinylpyrrolidone (PVP), citing Example 1.

Dansereau, like Blume, contains no disclosure, that would lead one or ordinary skill in the art to overcome the deficiencies of prior art guaifenesin tablets and thus provides no disclosure of tableting conditions, nor even granulation formulations relating to particle size or particle size distributions. At best, Dansereau could be said that it is possible to tablet guaifenesin with a PVP binder, but provide no other teaching of the limitations of the claimed invention.

Recognizing these deficiencies, the Examiner attempts to combine Blume and Dansereau with Wilber; or alternatively Wilber and Troy. However, neither of these alternatives establish a prima facie case of obviousness.

Rejections based upon 35 U.S.C. 103 (a) are factual in nature. The Examiner has the initial burden of establishing the faetual bases of the limitations reeited in the elaims.

Rejections is based on 35 U.S.C § 103 must rest on a factual basis; *In re Warner*, 379 F.2d 1011 (CCPA 1967)

Thercin the court stated, *Warner, supra* at 1017:

"In making such rejections, the Examiner has the initial duty of supplying the requisite factual basis and may not, beeause of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply defieiencies in the factual basis".

For example, while it is apparent that the Examiner's citation to Wilber et al. is aimed at teaching an agglomerate of the elaimed partiele range, it appears that the Examiner clearly miscomprehends Wilber et al. and any attempt at relianee on Wilber et al., is clearly misplaced, insofar as the portion cited by the Examiner e.g., column 4, lines 44-48, is not direeted to an agglomerate at all, and eertainly not an agglomerate comprising guaifenesin and a binder, but rather is to the physical properties of the rheology modified polymer or co-polymer alone.

If the Examiner would have read beyond line 48, of eolumn 4 it is clearly stated by Wilber et al. that "desirably, the particle or granular size of the one or more polymers or co-polymers can be classified as falling within size ranges as defined by U.S. standard mesh screens. For example, the partiele size of the granulated rheology modifying polymers or copolymers is generally that which falls through 40 mesh but is retained on 200 mesh..." (compare these mesh sizes with the corresponding micrometer equivalents in the aforementioned Perry's Chemical Engineer's Handbook in the Evidence Appendix).

Although the Examiner needs to find an agglomerate of the particle size as claimed, all that Wilber et al teach is the rheology modifying polymer or copolymer having the described partiele size identified at column 4 lines 48 to column 5 line 10. If the Examiner would have continued her reading through the potential active ingredients which can be incorporated with the

reheology modified polymer or copolymer, beginning at eolumn 5, line 53 through column 7, line 49, it will be seen that Wilber et al. only suggest that "the slightly cross-linked one or morc reheology modifying polymer or copolymers [having the particle size deseribed above at eolumn 4, lines 48 to column 5, line 10], the one or more active ingredients [of no speeified particle size] as well as the one or more excipients are mixed in any eonventional manner to produce a blend" see column 7, lines 58-61. The partiele sizes of the resulting blends are never disclosed. Thus, there is absolutely no disclosure of the particle size of the resulting agglomerate of an active ingredient and of reheology modified polymer or copolymer in Wilber et al. Of eourse, no tableting limitations, sueh as a press of no more than 2.5 tons, nor the resulting friability, hardness or capping properties of the resulting tablet are provided by the Wilber et al diselosure.

Therefore, while the Examiner believes that shc was citing particle sizes of an agglomerate of a guaifenesin and binder, all that she was citing was the particle size of the binder absent the guaifenesin. When the prior art does describe the blending of the guaifenesin and binder, his disclosure is fatally defective as to the particle size of any resulting agglomeration of guaifenesin and binder, is silent as to the parameters upon which the tableting press operates and clearly does not specify the conditions recited in the elaims and is similarly silent s to the propertics of the resulting tablet.

Troy is not even concerned with guaifenesin tablets.

Troy is not at all direetcd to compositions eomprising guaifensin, but rather tableting sugar. In fact, Troy is solely directed to compressing sugar agglomerates for produetion of tablets (see eolumn 1, linc 53-55) and would not at all teach those skilled in the art how to form a high eontent particulate guaifenesin composition comprising between about 85- 97.5% by weight guaifenesin as instantly elaimed in the independent claim.

All that the Examiner has attempted to do is find isolated bits and pieces of the invention from among the collection of art that the Examiner has searched, but even when that collection is combined, it still does not establish the limitations of the claimed invention. For examplc, the

Examiner attempts to cite Troy as showing agglomerates ranging in particle size from "about 325 to about 12 mesh" [about 1.68mm to about 44 microns-source Perry's Chemical Engineers Handbook sixth edition, cited in the Evidence Appendix] and column 1, lines 59-61 of Troy. However, such teachings do not correct the deficiencies of Blume and Dansereau. Applicants's claims and particularly the particle size distribution as recited in claim 37 clearly distinguish the particle size distribution as limitations of the claims. More importantly, Troy et al is directed to tableting sugar, not guaifenesin and thus his teaching of agglomerate size for sugar has no relation to the instantly claimed invention.

Accordingly, there is nothing in the proposed combination of references that would even hint at producing a high weight guaifenesin tablet for agglomerates of guaifenesin and polyvinyl pyrrolidone from a composition as instantly claimed. Thus, it can be seen that even though the Examiner has cobbled together 4 references, the totality of the teachings of these references still fail to show either: the percentage of guaifenesin or the particle size distribution of agglomerates of guaifenesin and polyvinylpyrrolidone binder or the properties of the resulting tablets. Thus, there can clearly be no prima facie case of obviousness established for the claimed invention.

As neither Troy nor Wilber, individually or collectively teach that control of granulation size of a guaifenesin containing flowable particulate composition overcomes the problems of prior art guaifenesin containing compositions (as in Blume and Dansereau) their combination with the Troy and/or Wilber references, still fails to teach the limitations of the claimed invention.

(viii) CONCLUSION

Again, the Examiner's statement of obviousness is merely conclusory but she makes no attempt at satisfying her burden of establishing a factual basis to support the naked conclusion of obviousness.

For the foregoing reasons, reversal of all rejections by the Board are respectfully requested.

(ix) CLAIMS APPENDIX

A copy of the claims on Appeal can be found in claims Appendix

(x) EVIDENCE APPENDIX

A copy of the excerpt from Perry's Chemical Engineer's Handbook, sixth Ed, referenced in the Brief is attached.

(xi) RELATED PROCEEDING APPENDIX

Not applicable

Respectfully submitted,

Thomas P. Pavelko

Date: August 24, 2010
Atty Docket No. 8439.017.US0000

APPENDICES

The following Appendices are attached to and made a part of this brief:

Appendix A	Claims on Appeal
Appendix B	Evidence-Excerpt from Perry's Chemical Engineers Handbook, sixth Edition
Appendix C	Related Proceedings (N/A)

APPENDIX A: Claims on Appeal

2. The tablet of claim 37, wherein the composition comprises guaifenesin, polyvinlpyrrolidone binder, a solubilizer, a glidant, and a lubricant.

3. The tablet of claim 37, wherein the composition comprises guaifenesin, polyvinylpyrrolidone binder, a maltodextrin, a silica, and stearic acid.

4. The tablet of claim 37, wherein the composition, based on the total weight of dry ingredients, from about 85 to about 97.5 percent by weight guaifenesin, from about 1.0 to about 7 percent by weight polyvinylpyrrolidone binder, from about 0.2 to about 4 percent by weight of a solubilizer or a disintegrant or a solubilizer and a disintegrant, from about 0.1 to about 2 percent by weight of a glidant, and from about 0.1 to about 2 percent by weight of a lubricant.

8. The tablet of claim 37, wherein the composition exhibits a flow rate of greater than or equal to 6.5 grams per second, as measured using a VanKel flowmeter.

33. The tablet of claim 37, wherein the composition comprises, based on the total weight of dry ingredients, from about 85 to about 97.5 percent by weight guaifenesin, from about 1.0 to about 7 percent by weight polyvinylpyrrolidone binder, and from about 0.2 to about 4 percent by weight of solubilizer, or disintegrant, or solubilizer and disintegrant.

34. The tablet of claim 33, wherein the composition further comprises from about 0.1 to about 2 percent by weight of a glidant, and from about 0.1 to about 2 percent by weight of a lubricant.

37. A tablet formed by compressing in a tableting press a free flowing granular composition comprising an agglomerate of guaifensesin and a binder therefore, said binder comprising from about 1.0 to about 7% by weight polyvinylpyrrolidone, and from about 0.2 to about 4% by weight of solubilizer, or distintegrant, or solubilizer and disintegrant; and from about 0.1 to about 2 wt % of a lubricant; wherein the free flowing agglomerate exhibits a flow rate greater or equal to 6.5 grams per second as measured in a VanKel flowmeter and direct compression tableted in a tableting press operating at no more than 2.5 tons, to produce a tablet exhibiting less than 1% friability, a hardness in the range of 10.3 to 17.0 kp, and resistant to capping, said composition comprising particles having a sieve analysis, based on the total weight of the components of the composition, wherein 0% by weight of the particles exhibit a particle size greater than 425 micrometers and greater than about 85% by weight of the particles exhibit a particle size of greater than about 45 micrometers, and the composition comprises from about 85% by weight to about 97.5% by weight guaifenesin.

APPENDIX B: Evidenee Appendix under 37 CFR §41.37(c)(1)(ix)

Perry's Chemical Engineer's Handbook, sixth Ed

PERRY'S CHEMICAL ENGINEERS' HANDBOOK

SIXTH EDITION

McGraw-Hill Book Company

New York
St. Louis
San Francisco
Auckland
Bogotá
Hamburg
London
Madrid
Mexico
Montreal
New Delhi
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TABLE 21-6 U.S. Sieve Series and Tyler Equivalents (ASTM—E-11-61)

Sieve designation: Standard	Alternate	Sieve opening: mm.	in. (approx. equivalents)	Nominal wire diam.: mm.	in. (approx. equivalents)	Tyler equivalent designation
107.6 mm.	4.24 in.	107.6	4.24	6.40	0.2520	
101.6 mm.	4 in.†	101.6	4.00	6.30	.2480	
90.5 mm.	3½ in.	90.5	3.50	6.08	.2394	
76.1 mm.	3 in.	76.1	3.00	5.80	.2283	
64.0 mm.	2½ in.	64.0	2.50	5.50	.2165	
53.8 mm.	2.12 in.	53.8	2.12	5.15	.2028	
50.8 mm.	2 in.†	50.8	2.00	5.05	.1988	
45.3 mm.	1¾ in.	45.3	1.75	4.85	.1909	
38.1 mm.	1½ in.	38.1	1.50	4.59	.1807	
32.0 mm.	1¼ in.	32.0	1.25	4.23	.1665	
26.9 mm.	1.06 in.	26.9	1.06	3.90	.1535	1.050 in.
25.4 mm.	1 in.†	25.4	1.00	3.80	.1496	
22.6 mm.	⅞ in.	22.6	0.875	3.50	.1378	0.883 in.
19.0 mm.	¾ in.	19.0	.750	3.30	.1299	.742 in.
16.0 mm.*	⅝ in.	16.0	.625	3.00	.1181	.624 in.
13.5 mm.	0.530 in.	13.5	.530	2.75	.1083	525 in.
12.7 mm.	½ in.†	12.7	.500	2.67	.1051	
11.2 mm.*	7/16 in.	11.2	.438	2.45	.0965	.441 in.
9.51 mm.	⅜ in.	9.51	.375	2.27	.0894	.371 in.
8.00 mm.*	5/16 in.	8.00	.312	2.07	.0815	2½ mesh
6.73 mm.	0.265 in.	6.73	.265	1.87	.0736	3 mesh
6.35 mm.	¼ in.†	6.35	.250	1.82	.0717	
5.66 mm.*	No. 3½	5.66	.223	1.68	.0661	3½ mesh
4.76 mm.	No. 4	4.76	.187	1.54	.0606	4 mesh
4.00 mm.*	No. 5	4.00	.157	1.37	.0539	5 mesh
3.36 mm.	No. 6	3.36	.132	1.23	.0484	6 mesh
2.83 mm.*	No. 7	2.83	.111	1.10	.0430	7 mesh
2.38 mm.	No. 8	2.38	.0937	1.00	.0394	8 mesh
2.00 mm.*	No. 10	2.00	.0787	0.900	.0354	9 mesh
1.68 mm.	No. 12	1.68	.0661	.810	.0319	10 mesh
1.41 mm.*	No. 14	1.41	.0555	.725	.0285	12 mesh
1.19 mm.	No. 16	1.19	.0469	.630	.0256	14 mesh
1.00 mm.*	No. 18	1.00	.0394	.580	.0228	16 mesh
841 micron	No. 20	0.841	.0331	.510	.0201	20 mesh
707 micron*	No. 25	.707	.0278	.450	.0177	24 mesh
595 micron	No. 30	.595	.0234	.390	.0154	28 mesh
500 micron*	No. 35	.500	.0197	.340	.0134	32 mesh
420 micron	No. 40	.420	.0165	.290	.0114	35 mesh
354 micron*	No. 45	.354	.0139	.247	.0097	42 mesh
297 micron	No. 50	.297	.0117	.215	.0085	48 mesh
250 micron*	No. 60	.250	.0098	.180	.0071	60 mesh
210 micron	No. 70	.210	.0083	.152	.0060	65 mesh
177 micron*	No. 80	.177	.0070	.131	.0052	80 mesh
149 micron	No. 100	.149	.0059	.110	.0043	100 mesh
125 micron*	No. 120	.125	.0049	.091	.0036	115 mesh
105 micron	No. 140	.105	.0041	.076	.0030	150 mesh
88 micron*	No. 170	.088	.0035	.064	.0025	170 mesh
74 micron	No. 200	.074	.0029	.053	.0021	200 mesh
63 micron*	No. 230	.063	.0025	.044	.0017	250 mesh
53 micron	No. 270	.053	.0021	.037	.0015	270 mesh
44 micron*	No. 325	.044	.0017	.030	.0012	325 mesh
37 micron	No. 400	.037	.0015	.025	.0010	400 mesh

*These sieves correspond to those proposed as an international (I.S.O.) standard. It is recommended that wherever possible these sieves be included in all sieve analysis data or reports intended for international publication.

†These sieves are not in the fourth-root-of-2 series, but they have been included because they are in common usage.

Screening machines actuated by rotating unbalanced weights have a symmetrical shaft through the screen body with an unbalanced flywheel on each end. Counterweights on each flywheel, which may be moved in relation to the shaft, permit adjustment of the amplitude of vibration. On some makes of machines the complete shaft assembly is contained in a unit bolted to the top of the screen body.

The horizontal-type screen is actuated by an enclosed mechanism consisting of off-center weights geared together on short horizontal shafts. The mechanism is usually mounted between the side plates and above the screen body (Fig. 21-11).

Electrically Vibrated Screens These screens are particularly useful in the chemical industry. They handle very successfully many light, fine, dry materials and metal powders from approximately 4 mesh to as fine as 325 mesh. Most of these screens have an intense, high-speed (25 to 120 vibrations/s) low-amplitude vibration supplied by means of an electromagnet.

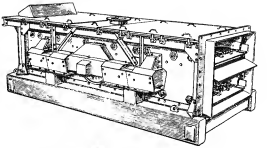

FIG. 21-10 Ty-Rock screen with air-seal enclosure. *(W. S. Tyler, Inc.)*

Typical of these is the Hum-mer screen used throughout the chemical industry. Figure 21-12 shows one used throughout the fertilizer industry for handling mixed chemical fertilizers.

Oscillating Screens These screens are characterized by low-speed oscillations [5 to 7 oscillations per second (300 to 400 r/min)] in a plane essentially parallel to the screen cloth.

Screens in this group are usually used from 0.013 m (½ in) to 60 mesh. Some light free-flowing materials, however, can be separated at 200 to 300 mesh. Silk cloths are often used.

Reciprocating Screens These screens have many applications in chemical work. An eccentric under the screen supplies oscillation, ranging from gyratory [about 0.05-m (2-in) diameter] at the feed end to reciprocating motion at the discharge end. Frequency is 8 to 10 oscillations per second (500 to 600 r/min), and since the screen is inclined about 5°, a secondary high-amplitude normal vibration of about 0.0025 m (⅛ in) is also set up. Further vibration is caused by balls bouncing against the lower surface of the screen cloth.

These screens are used extensively in the United States and are standard equipment in many chemical and processing plants for handling fine separations even down to 300 mesh. They are used to handle a variety of chemicals, usually dry, light, or bulky materials, light metal powders, powdered foods, and granular materials. They are not designed for handling heavy tonnages of materials like rock or gravel. Machines of this type are exemplified by Fig. 21-13.

Gyratory Screens These are boxlike machines, either round or square, with a series of screen cloths nested atop one another. Oscillation, supplied by eccentrics or counterweights, is in a circular or near-circular orbit. In some machines a supplementary whipping action is set up. Most gyratory screens have an auxiliary vibration caused by balls bouncing against the lower surface of the screen cloth. A typical machine is shown in Fig. 21-14. Machines of this type are operated continuously and can be located in line in pneumatic

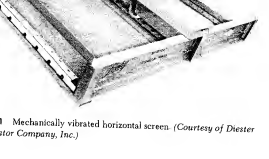

FIG. 21-11 Mechanically vibrated horizontal screen. *(Courtesy of Diester Concentrator Company, Inc.)*

APPENDIX C: Related Proceedings Appendix under 37 CFR §41.37(c)(1)(x)

N/A